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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,678	09/12/2003	Walter Schubert	S&H-010DX	4058

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EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/664,678	SCHUBERT, WALTER	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. If applicant desires benefit of a previously filed application under 35 U.S.C. 119(e), specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

2. The specification on page 1, section "Cross-reference to related applications", line 5 and 8 should be amended to reflect the status of the parent application USSN 09/802,305 and USSN 09/367,011, which are now US Patent No. 6,649,165 and US Patent No. 6,638,515, respectively.

3. Reference DE 19723690 cited on 1449 filed 12/12/2003 has been considered as far as discussed in the English Abstract.

4. The two US Patents cited in Form 892 were issued from the parent cases 09/802,305 and 09/367,011.

5. Claims 1-7 are pending and under consideration in the instant application.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of blocking the cytotoxic activity of Fcγ RIII-positive ALS specific cells in a patient with amyotrophic lateral sclerosis using soluble FcγRIII, does not reasonably provide enablement for the full breath of soluble Fcγ receptors and a method of treating a patient with ALS. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the claimed invention commensurate in scope with these claims.

8. The scope of claims 1-7 encompass a method of treating a patient with amyotrophic lateral sclerosis (ALS) by administering soluble Fcγ receptors that bind to IgG. The specification discloses that the blood of ALS patients contains mononuclear cells bearing CD16 and a different number of various other receptor proteins as listed in Table 1, and that the soluble Fcγ receptors block the cytotoxic activity of ALS-specific cells (see pages 5-6, in particular). CD16 is the international nomenclature of Fcγ RIII (see page 5, lines 24-26).

9. The specification does not provide sufficient guidance and direction with respect to soluble Fcγ receptors as broadly recited. There are three different classes of human Fcγ receptors (see last paragraph on page 3 of the specification), each of the receptor encodes by different genes and has different affinity for IgG (Nakamura et al, Expert Opin. Ther. Targets 2005: 9(1):169-190) (see page 171, Table 1, in particular). The specification does not enable any person skilled in the art to which it pertains to make and use the invention commensurate in scope of the instant claims.

10. Further, the specification does not adequately teach how to effectively treat ALS or reach any therapeutic endpoint in patients by administering soluble Fcγ receptors.

The example 1 on page 8 of the specification merely showed toleration test for soluble Fcγ preparations. It is not clear that reliance on the example 1 and the fact that ALS – specific cells having Fcγ receptors accurately reflect the efficacy of the claimed method of treating a patient with ALS. The state of the art recognizes that the mechanisms and processes responsible for the selective loss of motor neurons are still unknown and there is no cure or effective treatment presently exists (see abstract, McGeer et al. Biodrugs 2005;19(1)21-37, in particular). McGeer et al further teach that multiple pathways may contribute to ALS pathogenesis therefore combination drugs may be required for effective treatment (see page 35, last paragraph on the left column). In addition, Dalakas et al (Arch Neurol. 1994; 51:861-864 as cited in IDS) found that high-dose intravenous immunoglobulin, an agent known to block Fc receptors (see page 864, first paragraph in particular), was not effective in treating ALS (see conclusions, in particular). Furthermore, Rudnicki et al (Neurology 1987;37:335-337) reported that in an ALS patient with increase serum IgG, treatment with immuno-suppressive agents and plasmaphoresis, although lowered the serum concentration of IgG, was not effective in treating the patient. (see abstract, in particular).

11. Therefore, the specification disclosure does not enable one skilled in the art to practice the claimed invention without any undue amount of experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858F2d 731, 737, 8USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claims, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

13. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

14. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,649,165. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-7 of the '165 patent recite a method of blocking cytotoxic activity of FcγRIII positive immune cells in a ALS patient by infusing or injecting effective amount of IgG1/IgG3 binding soluble FcγRIII. The invention of the '165 patent encompasses one mechanism of treating a patient with ALS; it renders the claims 1-7 in the instant application obvious.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to

5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
August 3, 2005

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